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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Hisanori Kachi

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EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/501,401	Applicant(s) KACHI ET AL.	
	Examiner ERIC E. SILVERMAN	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6-19-08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' response filed 6/19/2008 has been received. Claims 8-19 are pending.

Preliminary Matters

Applicants' note on page 10 of the response that "the examiner has provided an English translation of Tables 2, 3 and 4 of the '433 reference. The translation of the '433 reference is a computer translation and contains or may contain errors." It is not certain which translation Applicants believe contains or may contain errors (the translation submitted by Applicant or the one prepared by the USPTO). Applicant then provides a "human translation" of a portion of paragraph [0006]. It is noted that this "human translation" is has not been made of record on an information disclosure statement, and thus is not evidence that can be relied upon when evidence is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-15 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10-273433 ("the 433 reference" or "433") in view of EP 1044672 ("672" or "the 672 reference").

Note that in the 433 reference, the USPTO has furnished its own translation of Tables 2, 3, and 4. The USPTO translation is cited on a PTO 892.

The 433 reference teaches compositions having an ester compound made from the esterification of glycerin, behenic acid, and eicosan dicarboxylic acid, as required by instant claims 1 and 6 (table 2, paragraph 0016). The compositions are oil-in-water emulsions (paragraph 0010), and are used as sunscreens (paragraphs 0007 and 0008, describing the compositions as having “ultraviolet ray absorbent is offered”). The ratio of the glyceryl, behenic acid, and eicosane diacid is commensurate with that required by instant claim 2 (paragraph 0025). The formulation, as expounded in table 2 (see USPTO translation of this table), includes octyl methoxycinnamate (a branched ester oil), liquid paraffin and squalane (oils other than ester oil, paraffin being a hydrocarbon oil) and PEG 6000 (a surfactant). Other excipients, such as stearates and dibutylene glycol are included, as per instant claim 7. The ratio of ester compound and ester oil is commensurate with instant claim 4. The amount of ester compound is between 0.1 and 20% by weight, which is believed to read on instant claim 3. Note that with respect to claim 3, because the claim is indefinite as discussed above, it is not clear what weight percents are needed to satisfy this claim. The weight percents of the 433 reference, as disclosed and suggested by table 2, meet these limitations as they are best understood.

What is lacking is the inorganic salt.

The 672 reference teaches oil-in-water cosmetics for application to skin or hair (paragraph 0002). Inorganic salts or amino acids are added to impart stability to W/O emulsion (abstract). The inorganic salts are chosen from those listed in claim 5, for example, sodium chloride, potassium chloride, aluminum sulfate, etc. Sodium and potassium chloride are alkali metal salts, as per instant claim 19.

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It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to include inorganic salts, particularly those taught by the 672 reference, in the compositions of the 433 reference. This combination is obvious for at least two reasons.

First, the 433 reference suggest a tangible advantage that could be gained from addition of such salts, namely, that the stability of the emulsion will increase. The artisan would thus find it obvious to add the salts and would expect a more stable emulsion.

Second, the claims represent no more than the combination of elements known in the art, where each element serves its art-recognized, predictable function. The additional agent in 433, the inorganic salts, are recognized as to act as a stabilizer. Based on the disclosure, the inorganic salts appear to serve the same function in the instantly claimed invention; there is no evidence to indicate any unexpected result.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive. Applicants argue that there is no motivation to add inorganic salts to the composition of the 433 reference, because the 433 reference teaches a complete, stable composition, to which the addition of stabilizing inorganic salts would be superfluous. At the outset, it is noted that the notion that obviousness can only be based on a teaching, suggestion or motivation to combine has recently been foreclosed by the courts. Even if all of Applicants' arguments about motivation were persuasive (they are not for reasons that follow), these arguments do not address the second reason for obviousness, namely

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that the claims are merely a combination of ingredients known in the prior art, where the ingredients have their recognized, predictable functions. The instant claims are no more than a combination of known sunscreen actives and excipients, wherein each ingredient serves its art recognized purpose.

With regard to motivation, Applicant argues that because the 433 reference teaches compositions that are stable (presumably because of the addition of the ester as described in claim 1 of instant claims), there is no need to add additional stabilizers such as the inorganic salts of 672. In response, there is motivation to combine materials in the art when those materials all serve or perform the same function. See MPEP 2144.06, see also *In re Kerkhoven*, 205 USPQ 1069,1072 (CCPA 1980).

Applicants' argument that one of skill in the art would not seek to improve upon a "complete" invention also fails in that, if this argument is applied generally, it reaches the ridiculous result that no one would ever have motivated to improve a functioning device, composition or method.

Claims 8-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10-273433 ("the 433 reference" or "433") in view of EP 1044672 ("672" or "the 672 reference") as applied to claims 8-15 and 17-19 above and in further view of US 5,567,420 ("420" or "the 420 reference").

What is lacking from the 433 reference and the 672 reference is a teaching of the oil other than ester oils of claim 16.

The 420 reference teaches sunscreen compositions, and suggests the use of emollients, such as olive oil and others of instant claim 16. Claim 16 of the 420 reference.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to add an emollient of instant claim 16 to the sunscreen composition of 433 and 672. Obviousness stems from the notion that the instant claims are merely a combination of known sunscreen actives and excipients, wherein each ingredient serves its predictable art recognized purpose. Obviousness also stems from 420's suggestion to add an emollient to a sunscreen composition, and the suggestion of the specific compounds of instant claim 16 to serve this purpose.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Eric E. Silverman
Art Unit 1618